UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOPURE CORPORATION SECURITIES LITIGATION	Civ. No. 03-12628 -NG

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO AMEND COMPLAINT

INTRODUCTION

The currently operative complaint (the "Consolidated Amended Complaint" or the "CAC") in this action was filed on July 23, 2004. The CAC alleged that throughout the period from March 17, 2003 through December 24, 2003 (the "CAC Class Period"), the Defendants issued false and materially misleading statements regarding Biopure and its development biologic product, Hemopure. The Plaintiffs have now moved to amend the CAC, by filing the Second Consolidated Amended Complaint ("SCAC").

Since its founding in 1984, the Defendant Biopure has devoted all of its resources, spending hundreds of millions of dollars, attempting to develop a biologic blood substitute which it calls Hemopure. (SCAC, ¶ 38). Hemopure has not been approved for human use in the United States, or anywhere else except South Africa. (SCAC, ¶ 2, 37). On July 31, 2002, Biopure submitted a biologic license application ("BLA") to the FDA, seeking regulatory approval to market Hemopure in the United States for patients undergoing orthopedic surgery (the "Hemopure BLA"). SCAC, ¶ 40. As part of the usual procedure in seeking such approval, Biopure submitted as part of the Hemopure BLA data from the Phase III clinical trials which it had conducted on the use of Hemopure for patients

undergoing orthopedic surgery, including adverse event data. SCAC, ¶ 41.

Gaining FDA approval of Hemopure has always been crucial to the continued viability of Biopure. SCAC, ¶ 38. In Biopure's quarterly report filed on Form 10-Q for the period ended January 31, 2003 (the "January 2003 10-Q"), the Defendants underscored the crucial importance to the Company of obtaining regulatory approval to market Hemopure for use in the treatment of human patients:

> Since inception, we have devoted substantially all of our resources to our research and development programs and manufacturing. We have been dependent upon funding from debt and equity financing, strategic alliances and interest income. We have not been profitable since inception and had an accumulated deficit of $392,713,000 as of January 31, 2003. We expect to incur additional operating losses over the next several years in connection with clinical trials, preparation of a marketing application for Hemopure in Europe and other markets and pre-marketing expenditures for Hemopure....
>
> * * * *
>
> The completed Phase III orthopedic surgery trial cost approximately $37,000,000 over the four years from protocol development to final report. These trial costs include costs incurred at nearly 50 hospitals, trial site monitoring, data management, regulatory consulting, statistical analysis, medical writing and clinical materials and supplies as well as Company personnel engaged in these activities. Costs incurred in filing the BLA include Company personnel and payments to third parties for manufacturing process documentation, medical consultants, regulatory consultants, integrating the safety and efficacy data bases for call clinical trials and pre-clinical studies. Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation....

SCAC, ¶ 39.

In summary, the CAC alleged that:

- the Defendants' numerous public statements during the CAC Class Period regarding Biopure, Hemopure and Biopure's Biologic License Application for

Hemopure (the "BLA" or the "Hemopure BLA"), were false, deceptive and misleading because the Defendants failed to disclose to the investing public that the FDA had placed a clinical hold on a proposed Phase II clinical trial of Hemopure in trauma patients **due to safety concerns arising out of data submitted by Biopure to the FDA in the Hemopure BLA.**

- the Defendants' numerous public statements during the CAC Class Period regarding Biopure's plans and intention to perform clinical studies regarding the use of Hemopure in trauma patients, were false, deceptive and misleading because the Defendants failed to disclose to the investing public that the FDA had placed a clinical hold on a proposed Phase II clinical trial of Hemopure in trauma patients **due to safety concerns arising out of data submitted by Biopure to the FDA in the Hemopure BLA.**

As is apparent from a reading of the CAC, and as discussed at length in Plaintiffs' Memorandum of Law in Opposition to the Defendants' Motions to Dismiss (Docket No. 70), the CAC more than adequately states claims upon which relief can be granted against all of the Defendants.[1]

On September 14, 2005, the Securities and Exchange Commission ("SEC") filed a securities fraud complaint against the defendants at bar, Biopure, Moore and Richman. That action is entitlted *Securities and Exchange Commission v. Biopure Corporation, Inc.,*

[1] Most of the legal discussion and analysis in that Memorandum, demonstrating the sufficiency of the CAC, applies with equal force to the sufficiency of the Second Consolidated Amended Complaint, which is the subject of the instant Motion to Amend. Rather than repeat those arguments herein, Plaintiffs respectfully refer the Court to that Memorandum and incorporate those arguments herein by reference thereto.

et als., No. 05-CA-11853-PBS (the "SEC Action"). The detailed factual allegations in the SEC's Complaint in the SEC Action (the "SEC Complaint"), and documents subsequently publicly filed by Biopure in the SEC Action, informed Plaintiffs and Plaintiffs' Counsel of:

- additional facts which support the securities fraud claims asserted in the Consolidated Amended Complaint;[2] and

- additional facts which demonstrate that the Defendants' public statements regarding Biopure, Hemopure and the Hemopure BLA from August 1, 2003 through the end of the Class Period were false, deceptive and misleading due to the Defendants' false, deceptive and misleading disclosure of, and description of, the FDA's July 30, 2003 letter to Biopure, in which the FDA set forth, in 34 single-spaced pages, the innumerable deficiencies it had found with, and the questions it had regarding, the Hemopure BLA.[3]

Accordingly, Plaintiffs prepared the Second Consolidated Amended Complaint, in which they added the numerous additional factual allegations that they had learned from the SEC Complaint and filings in the SEC Action and Plaintiffs filed the instant Motion to Amend, seeking leave of Court to file the SCAC. The Defendants have opposed the Motion to Amend, asserting that amending the complaint would be "futile" because the SCAC fails to adequately plead securities fraud by the Defendants. That assertion, in the face of the detailed facts alleged in the SCAC, is frivolous.

---

[2] Those additional facts also demonstrated that the Class Period should begin on April 9, 2003, not March 17, 2003 as set forth in the CAC. Accordingly, the SCAC defines the Class Period as April 9, 2003 through December 24, 2003.

[3] That letter is Exhibit B to the SCAC.

THE DEFENDANTS' ASSERTION THAT THERE IS SOMETHING "WRONG" WITH PLAINTIFFS ALLEGING FACTS IN THE SECOND CONSOLIDATED AMENDED COMPLAINT WHICH THEY LEARNED FROM THE COMPLAINT WHICH THE SEC FILED IN THE SEC ACTION IS UTTERLY WITHOUT MERIT.

The SEC, with the benefit of compulsory process during its investigation of the Defendants, was able to obtain documents and testimony which was unavailable to the Plaintiffs when they prepared the CAC, which shed substantial additional light on the Defendants' fraudulent conduct.[4] Some of those facts are detailed by the SEC in its Complaint; and some have been publicly filed in the SEC Action.

The Defendants assert that there is something "wrong" with the Plaintiffs using the facts that they learned from the SEC Complaint in preparing the SCAC. They argue, or at least infer, that this somehow violates Rule 11 and fails to "set forth the source of the information..." (Def. Mem. at 6).[5]

The Court in *De La Fuente v. DCI Telecomm., Inc.*, 259 F. Supp. 2d 250, 260 (S.D.N.Y. 2003), stated the obvious:

> I agree with plaintiff that there is nothing improper about utilizing information from the SEC as evidence to support private claims. Indeed, as plaintiff notes **"it would have been irresponsible for plaintiffs to have ignored the SEC's highly relevant allegations and findings" . . . The striking similarity between the SEC's allegations and plaintiff's allegations does not demonstrate that plaintiff lacked evidentiary support. Rather, the SEC allegations provided plaintiff with evidentiary support.** The PSLRA does not require that a plaintiff re-invent the wheel before filing a complaint; and one could argue that a complaint predicated on the results of an SEC investigation has far more "evidentiary support" than one based on rumor and

---

[4] The Plaintiffs have not had access to the Defendants' documents, including the documents produced by the Defendants to the SEC, due to the automatic stay of discovery under the PSLRA. *See* Plaintiffs' Motion to Lift the Automatic Stay of Discovery (Docket No. 80).

[5] If any violation of Rule 11 has occurred here, it is Defendants' counsel's frivolous assertion that Plaintiffs' counsel's use of the facts in the SEC Complaint violates Rule 11.

innuendo gleaned from "Heard on the Street."

(Emphasis added).[6]

THE DEFENDANTS BIOPURE, MOORE AND RICHMAN HAVE NOT CHALLENGED THE SUFFICIENCY OF THE SEC COMPLAINT IN THE SEC ACTION.

There is an old political expression, "judge us by what we do, not by what we say."[7] That adage is applicable here, with respect to the assertions by the Defendants Biopure, Moore and Richman that the SCAC fails to adequately plead securities fraud against them. The SCAC contains numerous factual allegations, including but not limited to all of the factual allegations contained in the SEC Complaint in the SEC Action against the Defendants Biopure, Moore and Richman, which is fully incorporated into the SCAC by reference. (*See* introductory paragraph of the SCAC and Exhibit A thereto). Nevertheless, while those Defendants assert here that the SCAC does not adequately plead securities fraud, they did not move to dismiss the SEC's Complaint against them.[8] Rather, they have

---

[6] The Defendants also make the "red herring" argument that the Court cannot take judicial notice of the facts in the SEC Complaint. But, of course, no one is asking the Court to do so. Plaintiffs only ask the Court, as is always the case in judging the sufficiency of pleadings, to assume that all of the facts alleged in the SCAC, including those alleged in the SEC Complaint which are incorporated into the SCAC by reference, are true in deciding the sufficiency of the SCAC. *In re Credit Suisse First Boston Corp.*, 431 F.3d 36, 45 (1st Cir. 2005) ("In considering a motion to dismiss, the district court is bound to 'assume the truth of all well-pleaded facts and indulge all reasonable inferences that fit the plaintiff's stated theory of liability.'"), citing *In re Colonial Mortg. Bankers Corp.*, 324 F.3d 12, 15 (1st Cir.2003): *Arturet-Velez v. R.J. Reynolds Tobacco Co.*, 429 F.3d 10, 13 (1st Cir. 2005).

[7] Plaintiffs' counsel believes it was coined by former Attorney General John Mitchell.

[8] Those Defendants have filed a motion for summary judgment regarding one part of one factual issue in the case, implicitly conceding that all of the other allegations in the SEC Complaint are well pleaded and will have to be resolved by a jury, at trial.

filed answers to the SEC Complaint.[9]

It should be noted that the requirements for pleading securities fraud by the SEC and the requirements for the Plaintiffs at bar are functionally the same. The SEC must meet the requirements of Rule 9(b), F. R. Civ. P. *S.E.C. v. Druffner,* 353 F.Supp.2d 141, 148 (D.Mass. 2005) ("Because the SEC's allegations rest on fraud, the complaint must satisfy the requirements of Rule 9(b)."); the Plaintiffs must meet the requirements of both Rule 9(b) and the PSLRA, which the First Circuit has held are the same. *Greebel v. FTP Software, Inc.,* 194 F.3d 185, 193 (1st Cir. 1999) (the PSLRA's pleading standard is "congruent and consistent" with pre-existing Rule 9(b) pleading standards in the First Circuit); *In re Art Technology Group, Inc. Securities Litigation*, 394 F. Supp.2d 313, 317 (D.Mass. Gertner, J., 2005) (the "PSLRA established strict pleading standards for such lawsuits, which are consistent with the First Circuit's preexisting standards for pleading securities fraud under Fed.R.Civ.P. 9(b)"). Hence, the Court in the SEC Action, on a motion to dismiss, would have judged the sufficiency of the SEC Complaint against the same standard as applies to the sufficiency of the SCAC here.

It is puzzling, at best, how the Defendants can purport, in good faith, to be arguing that the SCAC (which incorporates the SEC Complaint) fails to adequately plead a securities fraud claim against them, when they have implicitly acknowledged in the SEC Action that the SEC Complaint is sufficient under the same pleading standards.

---

[9] *See* docket entries 15, 18 and 19 in the Docket Sheets for the SEC Action, attached hereto as Exhibit A.

THE DEFENDANTS UTTERLY FAIL TO UNDERSTAND OR ACKNOWLEDGE THAT THERE IS ALWAYS TO DUTY TO DISCLOSE IN ORDER TO MAKE STATEMENTS BEING MADE NOT MISLEADING.

The Defendants' conduct, as described in detail in the SCAC, and their "duty to disclose" arguments in opposition to the motion to amend, reflect a fundamental misunderstanding of both the letter and spirit of the federal securities laws. The Defendants ignore the fundamental principle that one cannot make misleading and deceptive statements; and one always has a duty to disclose material facts if failing to do so would make statements made by the Defendants misleading. This principle is clearly stated in Rule 10b-5, which makes it unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). This principle is also firmly enshrined in case law. *See, e.g., In re Cabletron Systems, Inc.*, 311 F.3d 11, 36 (1st Cir. 2002) ("While a company need not reveal every piece of information that affects anything said before, it must disclose facts, "if any, that are needed so that what was revealed [before] would not be 'so incomplete as to mislead.'"") (citations omitted); *Roeder v. Alpha Industries, Inc.* 814 F.2d 22 (1st Cir. 1987) ("When a corporation does make a disclosure-whether it be voluntary or required-there is a duty to make it complete and accurate. . . . 'If . . . a company chooses to reveal relevant, material information even though it had no duty to do so, it must disclose the whole truth.'") (citations omitted).

A review of only a few of the allegations in the SCAC demonstrate that the Defendants repeatedly made misleading, if not objectively false, statements, regarding the Hemopure BLA, and that their failure to disclose material facts regarding their

communications about Hemopure and the Hemopure BLA with the FDA, rendered their public statements demonstrably deceptive and misleading. As the Court will see, these facts (most if not all of which are undisputable), do not only, easily, satisfy any and all pleading standards for a securities fraud complaint; these facts, if placed in evidence at trial, without more, would be more than sufficient evidence of fraud by the Defendants to require the Plaintiffs' securities fraud claims to be sent to the jury.

As pleaded in detail in the SCAC, Biopure was utterly dependent upon and at risk with respect to its Hemopure BLA. As summarized in the SCAC:

> 44. In light of the history and the nature of Biopure's business, the most critical and material information about Biopure during the Class Period was the status of the Hemopure BLA, including all facts which bore on when the FDA would rule on the Hemopure BLA and the likelihood that the FDA would (or would not) approve the BLA, thereby approving (or not approving) Biopure's sale of Hemopure in the United States for use with orthopedic surgery patients....

See also SCAC, ¶ 39.

The Defendants received extremely bad news from the FDA regarding the Hemopure BLA on April 9, 2003. Specifically:

> 46. On or about April 9, 2003, FDA staff members contacted Defendant Richman, Biopure's primary contact person with the FDA, by telephone concerning the INDA. **They informed him that FDA was imposing a clinical hold, barring Biopure from initiating any clinical trials connected with the trauma INDA, due to the "safety concerns" arising from data related to the BLA clinical trials and based upon "a preliminary assessment of the BLA." In particular, the FDA staff members expressly referred to data concerning serious adverse events that were experienced by BLA clinical trial participants, and stated that "the trial was on hold for safety and that in FDA's judgment it is unsafe to put this product in this patient population at this time."**

Thereafter, the FDA reaffirmed that clinical hold and the expressed safety concerns

regarding Hemopure, which precipitated that clinical hold, on April 25, 2003 (SCAC, ¶ 64) and May 30, 2003 (SCAC, ¶ 77).

During this time period, the Defendants made numerous public statements in SEC filings and conference calls that were inconsistent with the FDA's clinical hold and that were manifestly misleading and deceptive because of the Defendants' failure to disclose to the public the FDA's clinical hold and the FDA's reasons therefor. For example, on April 11, 2003, just two days after the FDA's above quoted communication with the Defendant Richman, advising the Defendants of the FDA's clinical hold, the Defendants made the following statement in a Registration Statement filed with the SEC:

> **...We believe that our completed pivotal Phase III clinical trials are consistent with the FDA's most recent guidance on** the design and efficacy and **safety endpoints required for approval of products such as Hemopure for use in surgical indications.** (Emphasis added.) [Footnote omitted]

(SCAC, ¶ 53).

The Defendants repeated that false and deceptive statement in Registration Statements or amendments filed with the SEC on April 16, 2003, June 19, 2003 and July 2, 2003. All of those SEC filings were signed by all of the Individual Defendants except Richman. (SCAC, ¶ 56).

The Defendants also lied to the investing public in a May 22, 2003 investor conference call, during which the Defendant Moore said:

> a. "...we continue to be very hopeful of an [FDA] response on our [biologic] license application by mid-year or sooner, and **we continue to not be aware of any major issues with that application at this time....**"
>
> b. "On FDA I'll just reiterate, I guess, at our last quarter we ...

> had answered all FDA questions and **we were unaware of any major issues. Fundamentally we're in the same place now.**"
>
> c. **"We continue to say we are not aware of anything that would cause undue delay** [in receiving a response from the FDA to the Hemopure BLA]..."

(SCAC, ¶ 73).

Let's be clear. In asserting that the SCAC fails to adequately plead securities fraud, the Defendants are asking this Court to hold, as a matter of law, that those statements – in the face of the FDA's clinical hold and its stated reasons therefore – were not misleading to the investing public. That is preposterous!

On July 30, 2003, the Defendants received even more devastating news from the FDA regarding both the clinical hold and the Hemopure BLA. Specifically, as set forth in the SCAC:

> 98. On July 30, 2003, Biopure received two highly significant letters from the FDA. One was a letter once again refusing to lift the clinical hold on the Trauma Clinical Trials (the "July 30, 2003 Trauma Clinical Trials Letter"). It was received by Defendants Moore and Richman on or about July 30, 2003 and about which Biopure's General Counsel was made aware no later than July 31, 2003. The other was FDA's Complete Response Letter (the "Complete Response Letter"), Exhibit B hereto...
>
> 100. The Complete Response Letter's opening sentences set forth the FDA's unambiguous rejection of the Hemopure BLA, stating:
>
> > The Center for Biologics Evaluation and Research (CBER) has completed the review of all submissions made relating to your Biologics License Application....
>
> 101. The Complete Response Letter also summarized the numerous deficiencies which the FDA found in Biopure's Hemopure BLA - a process which took the FDA **34 single-spaced pages** to accomplish. See Exhibit B. Altogether, the Complete Response Letter contained over **220** individual deficiencies and questions concerning Biopure's clinical trials and data

submitted in support of the Hemopure BLA and concerning the safety and efficacy of Hemopure. Id.

104. In the July 30, 2003 Trauma Clinical Trials Letter, the FDA once again refused to lift the clinical hold it had placed on the Trauma Clinical Trials because, in the FDA's words, **"human subjects are or would be exposed to an unreasonable and significant risk of illness or injury."** In support of that conclusion, the FDA cited many of the same deficiencies, questions, and concerns raised in the Complete Response Letter regarding the Hemopure BLA, the adequacy of controls concerning Biopure's prior Hemopure clinical trials and the analysis of the resulting data, and the safety of Hemopure.

105. The importance of Biopure's receipt, on July 30, 2003, of the Complete Response Letter and the July 30, 2003 Trauma Clinical Trials Letter cannot be overstated. The letters were lengthy, detailed, and together spelled out an insurmountable array of deficiencies in the Hemopure BLA which essentially signaled the death knell for Biopure's chances of **ever** gaining FDA approval for Hemopure. This defeat was especially pronounced given that as of July 30, 2003, Biopure had made two substantial submissions to the FDA requesting that it lift the clinical hold on the Trauma Clinical Trials, each of which failed to adequately address the FDA's safety concerns.

In the face of those devastating communications from the FDA, the Defendants lied to the investing public. They issued a press release on August 1, 2003, which:

- Did not disclose the FDA's clinical hold or the reasons therefore;
- Did not disclose the nature or extensive scope of the deficiencies which the FDA found with the Hemopure BLA;
- Deceived the marketplace as to the likely time-line for the further consideration of the Hemopure BLA by the FDA; and
- Blatantly and falsely stated that the Defendants were "encouraged" by the FDA's response to the Hemopure BLA.[10]

[10] Defendants' contention that their press release concerning the FDA Letter was a "soft statement of corporate optimism" that should not be actionable is misplaced. The law is well settled that

The Defendants full well knew that the July 30, 2003 letter from the FDA was very bad news; was in no way "encouraging;" and that to say they were "encouraged" by it was false and deceptive. **Biopure's outside counsel advised the Defendants, before the August 1, 2003 Press Release was issued, that the optimism expressed in the press release was unwarranted.** (SCAC, ¶ 107). The Defendants ignored that advice and published the August 1, 2003 Press Release.[11] The SCAC also pleads facts which demonstrate that the market was in fact deceived by the August 1, 2003 Press Release. The price of Biopure stock rose significantly in response to the August 1, 2003 Press Release. *See* SCAC, ¶¶ 112 and 114. Obviously, that would not have occurred had the market known the facts set forth in the two devastating May 30, 2003 letters from the FDA.

Once again, we need to be clear. In asserting that the SCAC fails to adequately plead securities fraud, the Defendants are asking this Court to hold, as a matter of law, that the August 1, 2003 Press Release – in the face of both of the FDA's May 30, 2003 letters to the Defendants – was not false, misleading and deceptive. That is absurd!

This discussion is, obviously, just a summary. The SCAC sets forth chronologically, in detail, numerous examples of public statements made by the Defendants which were false, deceptive and misleading because the Defendants failed to disclose and affirmatively hid from the investing public material information regarding the FDA's highly negative

---

an opinion or statement of belief is actionable if there are undisclosed facts that seriously undermine the accuracy of the statement. See, e.g., *Helwig v. Vencor, Inc.*, 251 F.3d 540, 557 (6th Cir. 2001), cert. denied, 536 U.S. 935 (2002). In fact, "the recent trend is to consider expressions of corporate optimism carefully." *Brumbaugh v. Wave Sys. Corp.*, 2006 WL 52751 at *5 (D. Mass. 2005)(Ponsor, J.).

[11] *See* SCAC, ¶ 109 for the full text of the August 1 press release, and SCAC, ¶ 110 for additional detailed reasons why that press release was false and deceptive.

communications with the Defendants regarding Hemopure and the Hemopure BLA. SCAC, ¶¶ 51-142.

THE INFERENCE IS REASONABLE, AND PLAINTIFFS ARE ENTITLED TO THE INFERENCE, THAT ALL OF THE INDIVIDUAL DEFENDANTS WERE AWARE OF THE FDA'S HIGHLY NEGATIVE COMMUNICATIONS REGARDING HEMOPURE AND THE HEMOPURE BLA.

In light of the extraordinary importance of the Hemopure BLA to Biopure and hence the extraordinary significance of the FDA communications with Biopure regarding Hemopure and the Hemopure BLA, the inference is more than reasonable that all of the defendant officers and directors of Biopure knew about the FDA communications when they signed SEC filings, approved Biopure press releases and participated in investor conference calls.

Of course, it is settled that: "In assessing a motion to dismiss for insufficient pleading, [a court] must read the complaint in the manner most favorable to the plaintiff, drawing reasonable inferences in the plaintiff's favor." See, e.g., Stone & Webster, 414 F.3d 187, 200 (1st Cir. 2005). Applying that principle, the Second Circuit in Cosmas v. Hassett, 886 F.2d 8 (2d Cir. 1989), held that in deciding a motion to dismiss by outside directors, a court should infer that they were aware of highly material, adverse information about the company. In Cosmas, the plaintiff sued eight corporate directors for securities fraud, alleging that the company in question was "principally engaged in the business of providing projection and video equipment and services in three markets" including an

"institutional market," which included customers in China. Id. at 10. The complaint further alleged that between April 1, 1985 and June 30, 1985, China "imposed significant import restrictions which restricted [the company's] sales to [Chinese] customers," but that the company and/or its directors nonetheless made false and misleading statements which did not disclose the Chinese import restrictions.

Under these circumstances, the Second Circuit found that the inference could be drawn that the director defendants were aware of the Chinese import restrictions and hence the complaint satisfied the *scienter* requirement of Rule 9(b). Id. at 13. The Second Circuit held:

> [C]omplaint alleges facts from which one can reasonably infer that sales to the PRC were to represent a significant part of [the company's] business. These facts give rise to a strong inference that the defendants, who the amended complaint alleges were directors of [the company], had knowledge of the [Chinese] import restrictions, since the restrictions apparently eliminated a potentially significant source of income for the company. In light of the strong inference that the defendants, at the time the allegedly fraudulent statements were made, had knowledge of the [Chinese] import restrictions, we conclude that the amended complaint alleges sufficient facts from which it can be inferred that the defendants had the requisite fraudulent intent.

Id at 13. *See also*, Goldman v. Belden, 754 F.2d 1059 (2d Cir. 1985).

THE SCAC MORE THAN ADEQUATELY PLEADS SCIENTER

Scienter is defined as a mental state embracing intent to deceive, manipulate or defraud. *Aaron v. Sec. & Exch. Comm'n*, 446 U.S. 680 (1980); *see also Ernst & Ernst v. Hochfelder*, 425 U.S. 195, 193 n.12 (1976). Section 21(D)(b)(2) of the PSLRA requires that a plaintiff state "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The standard

for pleading scienter in this Circuit is clear. In order to plead a "strong inference" of scienter, plaintiffs must plead defendants' knowledge **or** recklessness. *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 198-201 (1st Cir. 1999). Moreover, the PSLRA does "not mandate a particular test to determine scienter, " instead the court must analyze the particular facts of each individual case. *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 82 (1st Cir. 2002)(*citing Greebel* 194 F.3d at 196). Accordingly, as the First Circuit stated in *Aldridge*:

> [T]he plaintiff may combine various facts and circumstances indicating fraudulent intent to show a strong inference of scienter. As part of the mix of facts, the plaintiff may allege that the defendants had the motive ("concrete benefits that could be realized by the false statements and wrongful nondisclosures") and opportunity ("the means and likely prospect of achieving concrete benefits by the means alleged") to commit the fraud.

Id.

Moreover, plaintiffs need not prove up their allegations at the pleading stage or to allege more than can reasonably be expected at the pleading stage when all discovery is stayed. *See Cooperman v. Individual Inc*., 171 F.3d 43, 48-49 (1st Cir. 1999) ("We cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence."). As one Court recently emphasized, **"**[s]cienter may be proven and pled by reference to circumstantial evidence, for it is rare that perpetrators of fraud would confess outright . . . the circumstantial evidence (plus any other direct evidence) must still give rise to a 'strong inference,' but once it does so, no more is required to satisfy the PSLRA's scienter threshold." *In re Peoplesoft Sec. Litig.*, No. C99-00472 WHA, 2000 U.S. Dist. LEXIS 10953 at *9 (N.D. Cal. May 26, 2000), *citing In re Silicon Graphics Sec. Litig.*, 183

F.3d 970, 986 (9thCir. 1999), *reh'g en banc denied*, 195 F.3d 521 (1999).

Finally, the allegations and inferences of the SCAC should not be viewed separately to assess whether each allegation independently supports a strong inference of scienter. Rather, the question is whether the SCAC "considered in its entirety" states facts which give rise to scienter allegations. *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999)(emphasis added). "[W]hile mere allegations of motive and opportunity alone may be insufficient, together with additional factual support, evidence of motive and opportunity may establish a strong inference of scienter." *Aldridge*, 284 F.3d at 82; *accord Greebel*, 194 F.3d at 197.

The SCAC easily meets those requirements for scienter. The obvious discrepancy between what the Defendants knew about the FDA's communications regarding Hemopure and the Hemopure BLA, and what the Defendants told the investing public, in numerous SEC filings, telephone conferences and press releases, are particularized "... facts giving rise to a strong inference that the defendant[s] acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). But here, we have even more. The SCAC pleads facts which specifically demonstrate that the Defendants were purposely and intentionally lying to and deceiving the investing public regarding the FDA's July 30, 2003 letter regarding the Hemopure BLA.

As previously discussed, the Defendants sought advice regarding the FDA's July 30, 2003 letter and the August 1, 2003 Press Release with their outside counsel who specialized in FDA regulatory matters, before issuing the Press Release. The SCAC alleges in this regard as follows:

107. On or about July 31, 2003, Biopure, through its General

> Counsel, contacted outside legal counsel specializing in FDA regulatory matters to discuss the Complete Response Letter and a press release Biopure intended to issue. The draft press release stated that Biopure had received correspondence from the FDA, but did not identify it as being a "complete response letter." Outside counsel orally advised Biopure's General Counsel that he "didn't have time to read letter but looked like complete response [sic]," that the draft press release looked "unduly optimistic," and that issuance of the Complete Response Letter "30 days early in this context while true isn't great cause optimism [sic]." Biopure's General Counsel informed Defendants Moore and Richman of the substance of these comments by outside counsel.

Nevertheless, the Defendants ignored that advice and published the August 1, 2003 Press Release, which falsely stated that they were "encouraged" by the FDA's letter.

The Defendants' scienter is also apparent from their efforts to hide from the investing public the fact that the FDA's July 30, 2003 Letter regarding the Hemopure BLA was a "Complete Response Letter." The fact that it was a Complete Response Letter had significant regulatory and hence investment significance. The Defendants hid that fact from the investing public until December 11, 2003, when they issued a press release describing the letter as a "complete response letter." SCAC. ¶ 156.[12]

When they issued the August 1, 2003 Press Release, in which they did not describe the letter as a Complete Response Letter, the Defendants had already been told by their outside counsel that he thought it was a Complete Response Letter (SCAC, ¶ 107) and they had been told by the FDA that it was a complete response letter; that the FDA would take no further action on the Hemopure BLA unless and until Biopure responded to all of the 220 deficiencies noted by the FDA; and if Biopure so responded, the FDA would then have an additional six months thereafter to review the responses. (SCAC, ¶ 106)

[12] The price of Biopure stock dropped when the marketplace learned, from the December 11, 2003 Press Release, that the FDA's letter was a Complete Response Letter. *See* SCAC. ¶¶ 157-158.

Nevertheless, with the intent to deceive, the Defendants issued the August 1, 2003 Press Release.

The Defendants' later effort to hide from the investing public that the July 30, 2003 letter was a Complete Response Letter almost demonstrates their scienter. On September 12, 2003, Biopure filed a prospectus with the SEC that described the letter as a "Complete Response Letter." Biopure's stock promptly started to decline. The Defendants, knowing full well that the July 30, 2003 letter was a Complete Response Letter, nevertheless:

- emailed messages to investors that the characterization of the July 30, 2003 letter as a Complete Response Letter was a "mistake" by a "junior lawyer at a law firm" used by Biopure; and
- on September 15, 2003, amended the September 12, 2003 prospectus, deleting the reference to the July 30, 2003 letter as a Complete Response Letter.

(SCAC, ¶¶ 128-129).

The SCAC, in detailed factual pleading, demonstrates that the Defendants repeatedly went out of their way and bent over backwards to lie to, mislead and deceive the investing public. The facts alleged in the SCAC are not only sufficient to meet all applicable pleading standards, they would, if placed into evidence at trial, be more than sufficient to put the issue of the Defendants' scienter to the jury.[13]

[13] The significant insider trading, during the Class Period, by Defendants Biopure and Rauch, also creates a strong inference of scienter. SCAC, ¶¶ 170 -180. This is discussed in Plaintiffs' Memorandum of Law in Opposition to the Defendants' Motions to Dismiss (Docket No. 70) at pages 65 - 67.

CONCLUSION

For all of the legal and factual reasons set forth herein and in Plaintiffs' Memorandum of Law in Opposition to the Defendants' Motions to Dismiss (Docket No. 70), and particularly in light of the detailed factual pleadings in the SCAC, this Court should allow Plaintiffs' Motion for Leave to Amend the Complaint.

Dated: January 27, 2006 Respectfully submitted,

SHAPIRO HABER & URMY LLP

/s/ Edward F. Haber
Edward F. Haber BBO #215620
Theodore M. Hess-Mahan BBO #557109
Matthew L. Tuccillo BBO # 643336
53 State Street
Boston, MA 02109
(617) 439-3939

STULL, STULL & BRODY
Jules Brody
Howard T. Longman
6 East 45th Street
New York, New York 10017
(212) 687-7230

Co-Lead Counsel For
Lead Plaintiff and The Class

Certificate of Service

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent to those indicated as nonregistered participants on the 27th day of January, 2006.

/s/ Edward F. Haber
Edward F. Haber